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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,401	07/08/1999	ALESSANDRO SETTE	2473.0060008/paj/m-m	8008

50710 7590 12/23/2009

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.
1100 NEW YORK AVE.
WASHINGTON, DC 20005

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/350,401	SETTE ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-71* is/are pending in the application.

4a) Of the above claim(s) *65,68,70 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63,64,66,67,69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/09 has been entered.

2. Claims 65,68,70 and 71 are drawn to nonelected species as per the restriction requirements made in the previous Office Actions and are therefore withdrawn from consideration.

3. Claims 63,64,66,67,69 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 52,55,57,58,61,62 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the cancellation of said claims

6. Claims 64,66,67,69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1) There is no support in the specification as originally filed for the composition of claim 64/67. The specification discloses vaccines or pharmaceutical compositions containing a pharmaceutically acceptable carrier, but does not disclose the scope of

claim 64 which is a composition other than vaccine or pharmaceutical containing pharmaceutically acceptable carriers.

Regarding applicants comments, the cited passages of the specification are not drawn to immunogenic compositions containing a pharmaceutically acceptable carrier.

2) There is no support in the specification as originally filed for the recitation of "wherein said one or more second peptides is a cytotoxic T cell (CTL)- inducing peptide or a helper T cell (HTL)-inducing peptide" in claim 66/69. Regarding applicants comments, the aforementioned composition is not disclosed in the cited pages of the specification.

There is no support in the specification as originally filed for the scope of the claimed inventions (e.g. the claimed inventions constitutes new matter).

Regarding applicants comments, whilst the cited passages disclose vaccine compositions containing the components under consideration, the instant claims encompass nonvaccine compositions containing the aforementioned ingredients that are not disclosed in the specification. Regarding the cited passages of the specification, pages 18 and 41, said passages are not drawn to the particular composition recited in the instant claims. The example on page 84 is drawn to a vaccine composition which is not the composition under consideration in the instant claims.

3) There is no support in the specification as originally filed for the composition of claims 69. The specification discloses the peptide of claim 69 linked to a CTL epitope or contained in a vaccine composition, but does not disclose the claimed composition which is not a vaccine and wherein the peptides are not linked.

Regarding applicants comments, whilst the cited passages disclose vaccine compositions containing the components under consideration, the instant claims encompass nonvaccine compositions containing the aforementioned ingredients that are not disclosed in the specification. In addition, regarding the cited passage of page 84 of the specification, said passage refers to ""epitopes from the various disease associated sources" wherein the HTL peptides recited in the instant claims are not disease associated HTL. Regarding applicants comments, the quoted passage of the

specification from page 5 of the instant amendment states: "A polyepitopic peptide composition … **for the administration to individuals at risk for both HBV and HCV infection**.". Thus, the composition referred to in said passage is a vaccine.

7. The rejection of claim 61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in paragraph 5 of the previous Office action is withdrawn in view of the cancellation of said claim.

8. The rejection of claims 53 and 58 are under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons elaborated in the previous Office Action are withdrawn in view of the cancellation of said claims.

9. Claims 64 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed immunogenic composition containing a pharmaceutically acceptable carrier. The specification does not disclose how to use the instant invention for the in vivo treatment/prevention of HBV in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment/prevention of HBV infection in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment/prevention of HBV infection in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a immunogenic composition containing a pharmaceutically acceptable carrier wherein the only use for compositions containing a pharmaceutically acceptable carrier disclosed in the specification is to treat/prevent HBV infection. The substantial/real life use for the claimed inventions are preventing and treating HBV infection in humans. There is currently no known pharmaceutical composition containing a single HBV peptide for treating or preventing HBV in humans. Basalp et al. teach that the currently used HBV vaccine contains intact HBV surface antigen (HBs, see column 1, page 2).

The claimed invention does not contain intact HBs and only contains a single peptide derived from HBV polymerase. There is no evidence of record that intact polymerase (or the pol derived peptide recited in the claim) can be used to treat HBV infection in humans. Basalp et al. teach that antibody responses against HBs that are produced by the HBV vaccine are an important component of the mechanism of action of the HBV vaccine (se page 1, column 1, continued on page 2 and pages 4-6). There is no evidence of record that the peptide recited in the claim can elicit a protective antibody response for the treatment of HBV infection. In addition, the peptide recited in the claims does not bind most HLA alleles and therefore would not even elicit CTL in most individuals.

Thus, the state of the art is that it is highly unpredictable whether the peptide recited in the claims could be used as in a composition to treat/prevent HBV infection in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating HBV infection. Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat HBV in vivo in humans. Thus, use of a particular peptide for treatment/prevention of HBV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent malarial infection. Regarding Wands factor 6, the relative skill of those in the art is high (e.g. Ph.D. or M.D.). Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Regarding applicants comments, the claimed invention is drawn to a composition wherein the intended use for said composition disclosed in the specification is the in vivo treatment of disease in humans. Regarding applicants comments about other uses, as per the new matter rejection addressed above, the only compositions disclosed in the specification with a pharmaceutically acceptable carrier are pharmaceutical/vaccine compositions for treatment of disease. The claimed inventions are drawn to a composition that can be used to treat/prevent HBV infection. The substantial/real life use for the claimed inventions are preventing and treating HBV infection in humans. There is currently no known composition containing a single HBV peptide for treating or preventing HBV in humans. Basalp et al. teach that the currently used HBV vaccine contains intact HBV surface antigen (HBs, see column 1, page 2). The claimed invention does not contain intact HBs and only contains a single peptide derived from HBV polymerase. There is no evidence of record that intact polymerase (or the pol derived peptide recited in the claim) can be used to treat HBV infection in humans. Basalp et al. teach that antibody responses against HBs that are produced by the HBV vaccine are an important component of the mechanism of action of the HBV vaccine (se page 1, column 1, continued on page 2 and pages 4-6). There is no evidence of record that the peptide recited in the claim can elicit a protective antibody response for the treatment of HBV infection. In addition, the peptide recited in the claims does not bind most HLA alleles and therefore would not even elicit CTL in most individuals. Thus, the state of the art is that it is highly unpredictable whether the peptide recited in the claims could be used as a pharmaceutical composition to treat/prevent HBV infection in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating HBV infection. Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat HBV in vivo in humans. Thus, use of a particular peptide for treatment/prevention of HBV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent HBV infection. Regarding applicants comments, the claims encompass a

composition that only contains the particular peptide recited in the claims. Regarding applicants comments about Mizukoshi et al., said reference does not disclose use of the claimed inventions to treat or prevent HBV infection. In fact, said reference does not disclose the administration of any peptide to a patient. The reference refers to immune responses that are found in HBV patients against a plethora of different peptides. The reference does not teach that immunization with any one particular peptide can be used to treat/prevent HBV infection.

10. In view of newly submitted withdrawn claim 70, claim 63 is interpreted as encompassing the peptide recited in the claim attached to another peptide(s).
Claim 70 recites language identical to that recited in claim 63 and includes additional covalently linked peptides. Thus, applicant has implicitly defined the language of claim 63 as encompassing said peptide found in the context of a larger peptide.
Regarding applicants comments, the MPEP section 2173.05(a) states:

III. TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

*Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer**, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms.** See, e.g., Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice*

that the patentee intended to so redefine that claim term."); Hormone Research Foundation Inc. v. Genentech Inc., 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. See Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202, 64 PATENTABILITY ***2173.05(b)*** *2100-215 Rev. 5, Aug. 2006 USPQ2d 1812, 1818 (Fed. Cir. 2002).*

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The rejection of claims 41,52,53,55,57,58 under 35 U.S.C. 102(e) as being anticipated by Seeger et al. (US Patent 5,360,714) as evidenced by Pasek et al. for the reasons elaborated in the previous Office Action is withdrawn in view of the cancellation of said claims.

13. Claims 63,64,66,67 are rejected under 35 U.S.C. 102(e) as being anticipated by Seeger et al. (US Patent 5,360,714) as evidenced by Pasek et al.

Seeger et al. teach HBV pol protein wherein the peptide recited in the claims is found in HBV pol (see column 10, third paragraph, column 5, third paragraph, columns 11-12). The HBV pol protein contains multiple peptides (it is around 90kd) and the amino acids found in said molecule in addition to the peptide recited in the claims function as "linkers". The HBV molecule of 90kd would be expected to contain multiple T cell epitopes. The protein can be prepared in a buffer such as disclosed by Seeger et al., column 14, first complete paragraph wherein said buffer would be encompassed by A "pharmaceutically acceptable carrier". The art recognized that the peptide recited in the claims is found in HBV pol (see Pasek et al., Figure 2).

Regarding applicants comments, see section 10 of this Office Action.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644